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#12

In re Application of Olga Bandman et al. :
Serial No.: 09/556,178 :
Filed: April 20, 2000 : PETITION DECISION
Attorney Docket No.: PF-0417-2 DIV :
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This is in response to applicants' petition, filed July 17, 2002 under 37 CFR 1.144, requesting withdrawal of the restriction requirement set forth by the examiner.

BACKGROUND

A review of the file history shows that this application was filed under 35 U.S.C. 111(b) on April 20, 2000 as a divisional of application 09/368,408, filed August 4, 1999, which was a divisional of 08/967,364, filed November 7, 1997. The application, as filed, contained claims 1-20. On May 11, 2001, the examiner mailed a restriction requirement dividing the claims into 6 groups. The examiner further required election of a single polypeptide or nucleotide sequence for examination. In the response filed June 7, 2001, applicants elected Group I, claims 1, 2, 16 and 17, as drawn to the polypeptide of SEQ ID No: 1. Applicants traversed the restriction requirement on essentially the same grounds presented in the instant petition, discussed below.

On August 13, 2001 the examiner (a different examiner) mailed a first action on the merits. The examiner made the restriction final, clarifying the restriction requirement by stating that each individual polypeptide sequence (SEQ ID No.) is an independent and distinct invention.

Applicants responded on January 14, 2002, amending claims 1, 2, 16 and 17 and adding claims 21 and 22. Applicants continued to traverse the restriction requirement on the grounds discussed below. On April 17, 2002, the examiner mailed a final Office action. The examiner maintained the restriction requirement. Applicants filed a Notice of Appeal on July 23, 2002.

Claim 1, from which all the other elected claims depend, reads as follows:

1. An isolated polypeptide comprising an amino acid sequence selected from the group consisting of:
 - a) an amino acid sequence selected from the group consisting of SEQ ID NO: 1, SEQ ID NO: 3, and SEQ ID NO: 5,

- b) a naturally-occurring amino acid sequence having at least 90% sequence identity to an amino acid sequence selected from the group consisting of SEQ ID NO: 3 and SEQ ID NO: 5,
- c) a biologically-active fragment of an amino acid sequence selected from the group consisting of SEQ ID NO: 1, SEQ ID NO: 3, and SEQ ID NO: 5,
- d) an immunogenic fragment of an amino acid sequence selected from the group consisting of SEQ ID NO: 1, SEQ ID NO: 3, and SEQ ID NO: 5, and
- e) a naturally-occurring amino acid sequence having at least 98% sequence identity to the amino acid sequence of SEQ ID NO: 1.

DISCUSSION

From applicants' arguments, it appears that there is some confusion over whether the claims are subject to restriction or to election of species. The second examiner clearly stated that the claims were restricted because each SEQ ID No. is an independent and distinct invention. However, for the sake of clarity, the claimed invention groups are set forth below to reflect the position of the Office.

- I. Claims 1, 2, 16, 17, 20 and 21, as drawn to SEQ ID NO: 1, fragments thereof, and similar naturally occurring polypeptides. (This is the group elected by applicants.)
- II. Claims 1, 2, 16 and 17, as drawn to SEQ ID NO: 3, fragments thereof, and similar naturally occurring polypeptides.
- III. Claims 1, 2, 16 and 17, as drawn to SEQ ID NO: 5, fragments thereof, and similar naturally occurring polypeptides.
- IV. Claims 3-9, 11 and 12, as drawn to SEQ ID NO: 2, host cells, and a method of expressing a polypeptide.
- V. Claims 3-9, 11 and 12, as drawn to SEQ ID NO: 4, host cells, and a method of expressing a polypeptide.
- VI. Claims 3-9, 11 and 12, as drawn to SEQ ID NO: 6, host cells, and a method of expressing a polypeptide.
- VII. Claim 10, drawn to an isolated antibody.
- VIII. Claims 13-15, drawn to methods of detecting a target polynucleotide.
- IX. Claims 18 and 19, drawn to methods of screening agonists and antagonists.
- X. Claim 20, drawn to a method of screening expression altering compounds.

Claims 1, 2, 16 and 17 link inventions I, II and III. The restriction requirement among the

linked inventions is subject to the nonallowance of the linking claim(s), claims 1, 2, 16 and 17. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application.

Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

In the petition, as in their previous responses, applicants argue that the members of the Markush group are few in number. This argument is incorrect and unpersuasive. The claim encompasses 3 families of sequences, not 3 sequences as asserted by applicants. Besides searching for SEQ ID NO: 1, the examiner is required to search the prior art for similar naturally occurring sequences, as well as biologically active and immunogenic fragments of SEQ ID NO: 1. Thus the members of the Markush group are not few in number.

Applicants argue that the 3 families of claimed sequences have unity of invention because they share a common utility and share a substantial structural feature disclosed as being essential to that utility. This argument is not persuasive for two reasons. First, SEQ ID NO: 1 does not possess a patentable utility for the reasons set forth by the examiner in the two Office actions on the merits. Second, applicants have not pointed out any essential structural features shared by SEQ ID Nos. 1, 3 and 5.

Applicants argue that Markush claims may include independent and distinct inventions, citing MPEP 803.02. This argument is not persuasive because the claimed subject matter is not analogous to the example which follows the cited portion of the MPEP. The example concerns a group of compounds which each comprise a core "C" and a substituent "X," with X being defined by a Markush group. Applicants' argument fails because no common core sequence ("C") has been identified. Absent evidence that the three families share a common core sequence analogous to the core compound of the MPEP example, this argument is not persuasive.

Applicants argue that multiple nucleotide sequences were searched in the parent application. This argument is not persuasive because a different search is required in the instant application. The results of the nucleotide search are of little or no use to the examiner in evaluating the patentability of the claims presently under examination.

DECISION

Applicants's petition is **DENIED** for the reasons set forth above.

The time period for filing an appeal brief continues to run from the filing date of the Notice of Appeal.

Any request for reconsideration or review of this decision must be made by a renewed petition and must be filed within TWO MONTHS of the mailing date of this decision in order to be

considered timely.

Should there be any questions with regard to this letter please contact Bruce Campell by letter addressed to the Director, Technology Center 1600, Washington, DC 20231, or by telephone at (703) 308-4205 or by facsimile transmission at (703) 746-5006.

John Doll

Director, Technology Center 1600

A handwritten signature in cursive script, appearing to read "John Doll", written over the printed name.